EXHIBIT A

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2006-1393, -1394, -1395, -1396, -1415, -1416

CORDIS CORPORATION,

Plaintiff-Cross Appellant,

v.

MEDTRONIC AVE, INC.,

Defendant-Appellant,

and

BOSTON SCIENTIFIC CORPORATION
and BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Defendants-Appellants.

MEDTRONIC AVE, INC.,

Plaintiff-Appellant,

v.

CORDIS CORPORATION, JOHNSON AND JOHNSON,
and EXPANDABLE GRAFTS PARTNERSHIP,

Defendants-Appellees.

BOSTON SCIENTIFIC CORPORATION
and BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Plaintiffs-Appellants,

v.

ETHICON, INC., CORDIS CORPORATION,
and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,

Defendants-Cross Appellants.

Appeals from the United States District Court for the District of Delaware in consolidated cases 97-CV-550, 97-CV-700, and 98-CV-19, Judge Sue L. Robinson.

ORDER

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellant*, and the petition for rehearing, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on April 16, 2008.

FOR THE COURT,

Jan Horbaly
Clerk

Dated: 04/09/2008

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT
APR 09 2008
JAN HORBALY
CLERK

cc: William P. Atkins, George Badenoch
Eugene M. Gelernter

CORDIS CORP V MEDTRONIC AVE, 2006-1393,-1394,-1395,-1396,-1415,-1419
(DCT - 97-CV-550)

*Medtonic Ave, Inc.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2006-1393, -1394, -1395, -1396, -1415, -1416

CORDIS CORPORATION,

Plaintiff-Cross Appellant,

v.

MEDTRONIC AVE, INC.,

Defendant-Appellant,

and

BOSTON SCIENTIFIC CORPORATION
and BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Defendants-Appellants.

MEDTRONIC AVE, INC.,

Plaintiff-Appellant,

v.

CORDIS CORPORATION, JOHNSON AND JOHNSON,
and EXPANDABLE GRAFTS PARTNERSHIP,

Defendants-Appellees.

BOSTON SCIENTIFIC CORPORATION
and BOSTON SCIENTIFIC SCIMED, INC. (formerly known as Scimed Life Systems, Inc.),

Plaintiffs-Appellants,

v.

ETHICON, INC., CORDIS CORPORATION,
and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,

Defendants-Cross Appellants.

Appeals from the United States District Court for the District of Delaware in consolidated cases 97-CV-550, 97-CV-700, and 98-CV-19, Judge Sue L. Robinson.

ORDER

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ORDER

A combined petition for panel rehearing and for rehearing en banc having been filed by the Appellants, Boston Scientific Corporation, et al., and a response thereto having been invited by the court and filed by the Cross-Appellant and the petition for rehearing and response, having been referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc and response having been referred to the circuit judges who are in regular active service,

UPON CONSIDERATION THEREOF, it is

ORDERED that the petition for panel rehearing be, and the same hereby is, DENIED and it is further

ORDERED that the petition for rehearing en banc be, and the same hereby is, DENIED.

The mandate of the court will issue on April 16, 2008.

FOR THE COURT,

Jan Horbaly
Clerk

Dated: 04/09/2008

cc: William P. Atkins, George Badenoch
Eugene M. Gerlernter

CORDIS CORP V MEDTRONIC AVE, 2006-1393, -1394, -1395, -1396, -1415, -1419
(DCT – 97-CV-550)

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CORDIS CORPORATION, Plaintiff, v. ADVANCED CARDIOVASCULAR SYSTEMS, INC., GUIDANT CORPORATION, MEDTRONIC AVE, INC., BOSTON SCIENTIFIC CORPORATION, and SCIMED LIFE SYSTEMS, INC., Defendants. and ADVANCED CARDIOVASCULAR SYSTEMS, INC. Counterclaim Plaintiff. v. CORDIS CORPORATION and EXPANDABLE GRAFTS PARTNERSHIP, Counterclaim Defendants. and BOSTON SCIENTIFIC CORPORATION, and SCIMED LIFE SYSTEMS, INC., Counterclaim Plaintiffs. and MEDTRONIC AVE, INC., Counterclaim Plaintiff.	Civ. No. 97-550-SLR (Consolidated)

v.

CORDIS CORPORATION, JOHNSON & JOHNSON, and EXPANDABLE GRAFTS PARTNERSHIP.

Counterclaim Defendants.

MEDTRONIC AVE, INC.,

Plaintiff.

v. C.A. No. 97-700-SLR

CORDIS CORPORATION, JOHNSON & JOHNSON, and EXPANDABLE GRAFTS PARTNERSHIP.

Defendants.

BOSTON SCIENTIFIC CORPORATION,

Plaintiff.

v. Civil Action No. 98-19-SLR

ETHICON, INC.; CORDIS CORPORATION; and JOHNSON & JOHNSON INTERVENTIONAL SYSTEMS CO.,

Defendants.

EXPERT REPORT OF DAVID C. CUMBERLAND, M.D.

At the request of counsel for defendants Boston Scientific Corporation and SCIMED Life Systems, Inc., I hereby submit this report pursuant to Fed. R. Civ. P. 26(a)(2)(B).

I. QUALIFICATIONS

1. I am a Professor of Interventional Cardiology at the University of Sheffield in Sheffield, England. I am a Fellow of the Royal College of Radiologists, a Fellow of the Royal College of Physicians (Edinburgh), a Fellow of the Royal College of Surgeons, a Fellow of the European Society of Cardiology and a Fellow of the American College of Cardiology.

2. I first received training in percutaneous transluminal coronary angioplasty in 1980 and was Founder Chairman of the British Coronary Angioplasty Group. I have been regularly implanting peripheral stents since 1987 and coronary stents since 1990.

3. I perform approximately 400 interventional procedures per year, about 70% of which involve stenting. I have published numerous articles in the field of interventional cardiology, and co-lead a team performing experimental research into vascular biology and clinical research in interventional cardiology. I am a co-investigator in several international trials involving coronary stents, and I am principal investigator in several ongoing, and two completed, coronary stenting trials. My curriculum vitae provides further details on my qualifications and is attached at Tab 1.

II. MATERIALS CONSIDERED

4. In reaching the conclusions stated in this report, I have considered the following materials:

a. U.S. Patent 4,733,665 and corresponding Reexamination Certificate B1 4,733,665 (collectively, the "'665 patent");

b. U.S. Patent 4,739,762 and corresponding Reexamination Certificate B1 4,739,762 (collectively, the "'762 patent");

c. U.S. Patent 5,102,417 (the "'417 patent");

d. U.S. Patent 5,195,984 (the "'984 patent");

e. U.S. Patent 5,902,332 (the "'332 patent");

f. UK Patent Application 2,135,585 A (the "Wallsten patent");

g. U.S. Patent 3,657,744 (the "Ersek patent");

h. U.S. Patent 4,560,374 (the "Hammerslag patent");

i. U.S.S.R. Patent 660689 to Kononov;

j. Charles T. Dotter & Melvin P. Judkins, *Transluminal Treatment of Arteriosclerotic Obstruction*, 30 CIRCULATION 654-70 (Nov. 1964);

k. Charles T. Dotter, *Transluminally-placed Coilspring Endarterial Tube Grafts*, 5 INVESTIGATIVE RADIOLOGY 329-32 (Sept.-Oct. 1969);

l. Andreas R. Grüntzig, et al., *Nonoperative Dilatation of Coronary-Artery Stenosis*, 301 NEW ENGLAND JOURNAL OF MEDICINE 61-68 (July 1979);

m. D. Maass et al., *Radiological Follow-up of Transluminally Inserted Vascular Endoprostheses: An Experimental Study Using Expanding Spirals*, 152 RADIOLOGY 659-63 (Sept. 1984);

n. Kenneth C. Wright et al., Abstract, *Percutaneous Endovascular Stents: An Experimental Study*: 153(P) Radiology 206 (November 1984);

o. Julio C. Palmaz et al., Abstract, *Expandable Intraluminal Graft: A Preliminary Study*: 153(P) Radiology 329 (November 1984) (the "1984 Palmaz Abstract");

p. Julio C. Palmaz et al., Abstract, *Expandable Intraluminal Portocaval Shunt: An Experimental Study*: PROGRAM OF THE EIGHTY-FIFTH ANNUAL MEETING, THE AMERICAN ROENTGEN RAY SOCIETY, April 21-26, 1985, (the "April 1985 Palmaz Abstract");

q. Kenneth C. Wright et al., *Percutaneous Endovascular Stents: An*

Experimental Evaluation. 156 RADIOLOGY 69 (July 1985);

r. Julio C. Palmaz et al., *Expandable Intraluminal Graft: A Preliminary Study*, 156 Radiology 73 (July 1985) (the "1985 Palmaz Article");

s. Julio C. Palmaz et al., *Expandable Intrahepatic Portacaval Shunt Stents: Early Experience in the Dog*, 145 AJR 821 (October 1985) (the "Second 1985 Palmaz Article");

t. Chusilp Charnsangavej et al., Abstract, *Endovascular Stent for Vena Caval Stenosis: Laboratory Experiment and Potential Clinical Applications*, Program: 71st SCIENTIFIC ASSEMBLY AND ANNUAL MEETING OF THE RADIOLOGICAL SOCIETY OF NORTH AMERICA, November 17-22, 1985, 157(P) RADIOLOGY 66, 90 (November, 1985) (the "1985 Charnsangavej Abstract");

u. Michael J. Wallace et al., *Tracheobronchial Tree: Expandable Metallic Stents Used in Experimental and Clinical Applications*, 158 RADIOLOGY 309 (February 1986) (the "First Wire Strut Article");

v. Julio C. Palmaz et al., *Expandable Intraluminal Vascular Graft: A Feasibility Study*, 99 SURGERY 199 (Feb. 1986);

w. Julio C. Palmaz et al., *Atherosclerotic Rabbit Aortas: Expandable Intraluminal Grafting*, 160 RADIOLOGY 723 (Sept. 1986);

x. Chusilp Charnsangavej et al., *Stenosis of the Vena Cava: Preliminary Assessment of Treatment with Expandable Metallic Stents*, 161 RADIOLOGY 295 (November 1986) (the "Second Wire Strut Article");

y. Julio C. Palmaz et al., Abstract, *Balloon Expandable Intraluminal Grafting of Normal and Abnormal Renal Arteries: Experimental Study*, 161(P) RADIOLOGY 40

(November 1986):

z. Nancy Rollins et al., Abstract. *Expandable Metallic Stent in Atherosclerotic Vessels: An Experimental Evaluation*. 161(P) RADIOLOGY 40 (November 1986):

aa. Gary J. Becker et al., Abstract. *Simultaneous Angioplasty and Intraluminal Grafting with the Palmaz Expandable Intraluminal Graft*. 161(P) RADIOLOGY 40 (November 1986):

bb. Josef Rösch et al., Abstract. *Expandable Gianturco-Type Wire Stents in Experimental Intrahepatic Portacaval Shunts*. PROGRAM: "72nd SCIENTIFIC ASSEMBLY AND ANNUAL MEETING OF THE RADIOLOGICAL SOCIETY OF NORTH AMERICA." November 30 - December 5, 1986. 161(P) RADIOLOGY 40, 41 (November, 1986) (the "Monofilament Abstract"):

cc. Gerard Duprat, Jr. et al., Abstract. *Expandable Metallic (Gianturco) Stents in Small Vessels: An Experimental Evaluation*. 161(P) RADIOLOGY 40 (November 1986):

dd. Josef Rösch et al., *Experimental Intrahepatic Portacaval Anastomosis: Use of Expandable Gianturco Stents*. 162 RADIOLOGY 481 (February 1987) (the "First Monofilament Article"):

ee. Josef Rösch et al., *Gianturco Expandable Stents in Experimental and Clinical Use*. PROGRAM: TWELFTH ANNUAL COURSE ON DIAGNOSTIC ANGIOGRAPHY AND INTERVENTIONAL RADIOLOGY (Society of Cardiovascular and Interventional Radiology, San Diego, Ca.), March 23-26, 1987 (the "Second Monofilament Article"):

ff. David D. Lawrence et al., *Percutaneous Endovascular Graft: Experimental Evaluation*. 163 RADIOLOGY 357 (May 1987):

gg. Josef Rösch et al., *Modified Gianturco Expandable Wire Stents in*

Experimental and Clinical Use, 31 ANNALES DE RADIOLOGIE 100-03 (1988) (presented at CIRSE meeting, Porto Cervo, Sardinia, May 25-29, 1987);

hh. Chusilp Charnsangavej et al., *A New Expandable Metallic Stent For Dilatation of Stenotic Tubular Structures: Experimental and Clinical Evaluation*, 3 HOUSTON MEDICAL JOURNAL 41-51 (June 1987);

ii. Richard A. Schatz et al., *Balloon-expandable Intracoronary Stents in the Adult Dog*, 76 CIRCULATION, 450 (Aug. 1987);

jj. Josef Rösch et al., *Gianturco Expandable Wire Stents in the Treatment of Superior Vena Cava Syndrome Recurring After Maximum-Tolerance Radiation*, 60 CANCER 1243-46 (Sept. 1987);

kk. Richard A. Schatz & Julio C. Palmaz, *New Technology in Angioplasty: Balloon-Expandable Intravascular Stents*, 2 NEW DEVELOPMENTS IN MEDICINE, 59 (Sept. 1987);

ll. Julio C. Palmaz et al., *Normal and Stenotic Renal Arteries: Experimental Balloon-expandable Intraluminal Stenting*, 164 RADIOLOGY 705 (Sept. 1987);

mm. Charles Mullins, et al., *Implantation of Balloon- Expandable Intravascular Grafts by Catheterization in Pulmonary Arteries and Systemic Veins*, 77 CIRCULATION 188-99, (Jan. 1988);

nn. Julio C. Palmaz & Stewart R. Reuter, *Intravascular Stents: Basic Physical and Biological Properties*, *in* HANDBOOK OF THE EIGHTH INTERNATIONAL COURSE OF PERIPHERAL VASCULAR INTERVENTION 149-58 (mid-1990s);

oo. the Court's Memorandum Opinion dated 15 January 1999 and its Memorandum Order dated 18 June 1999;

pp. portions of the prosecution histories of the patents in suit, the parent '665 patent, and the reexaminations of those patents; and

qq. the Opening Brief in Support of the Motion by Defendants Boston Scientific Corporation and Scimed Life Systems, Inc. for Summary Judgment of Invalidity of U.S. Patent No. 5,102,417; Plaintiffs' Answering Brief in Opposition to that motion; BSC's and Scimed's Reply in further support of that motion; and the exhibits to those documents.

5. In addition to those materials, I have also reviewed my expert report from *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, C.A. No. IP 98-1108 C. H/G (S.D.In.) and my witness statement from *Boston Scientific Ltd. v. Palmaz*, CH 1997 B. Nos. 1495, 1496, 1493, 1497 (U.K. Ch. Div., Patents Ct.). The preparation of those reports required me to review materials in addition to those described specifically above in connection with this report.

III. SUMMARY OF OPINIONS

6. A "person" of ordinary skill in the art during the mid-1980s would have comprised a person or persons with the knowledge and skills of (i) a physician specializing in radiology, cardiology, cardiovascular surgery, or some related discipline, and (ii) an engineer having at least a bachelor's degree in mechanical or biomedical engineering or materials science, and experience in the design of implantable medical devices.

7. As of November 7, 1985, claims 23, 44, 51, and 52 of the '762 patent would have been obvious to a person of ordinary skill in the art who had before him the 1984 Palmaz Abstract, the Wallsten patent, and the Ersek patent.

8. In addition, and in the alternative, as of November 7, 1985, claims 23, 44, 51 and 52 of the '762 patent would have been obvious to a person of ordinary skill in the art who had before

him the 1984 Palmaz Abstract, the Wallsten patent, the Ersek patent, and the Hammerslag patent.

9. In addition, and in the alternative, as of November 3, 1986, claims 23, 44, 51 and 52 of the '762 patent would have been obvious to a person of ordinary skill in the art for the same reasons stated above, and in addition, would have been obvious if he had before him the 1985 Palmaz Article, and the Second 1985 Palmaz Article.

10. As of March, 28, 1988, claims 17, 18, 25 and 26 of the '417 patent would have been obvious to a person of ordinary skill in the art who had before him the '665 patent, the '762 patent, and the 1985 Palmaz Article.

11. In addition, and alternatively, the subject matter of claims 17, 18, 25 and 26 of the '417 patent would have been obvious to a person of ordinary skill in the art who had before him the '665 patent, the '762 patent, and the 1985 Palmaz Article and any of the following: the First Wire Strut Article, the Second Wire Strut Article, the First Monofilament Article, and the Second Monofilament Article.

12. As of October 4, 1988, claims 22 and 24 of the '332 patent would have been obvious to one of ordinary skill in the art who had before him the art described in paragraph 10 above in connection with the '417 patent.

13. In addition, and alternatively, as of October 4, 1988, claims 22 and 24 of the '332 patent would have been obvious to one of ordinary skill in the art who had before him the art described in paragraph 11 above in connection with the '417 patent.

14. In addition, and alternatively, the subject matter of claims 22 and 24 of the '332 patent would have been obvious to a person of ordinary skill in the art who had before him the '417 patent.

15. There is no description in the '332 patent of any connector other than the single,

straight connector shown and described in the '984 and '332 patents.

16. The success enjoyed by the Palmaz-Schatz stent in the United states was not related to the features described and patented in the '762, '417, and '332 patents. Rather, I understand that success to be due to the fact that the Palmaz-Schatz stent was the only balloon-expandable stent available on the U.S. market with FDA approval for elective, non-urgent use. Indeed, as soon as other balloon-expandable stents entered the U.S. market with similarly broad approval, the Palmaz-Schatz was displaced from the market.

IV. BASES FOR OPINIONS

A. Background

17. I expect to be asked to provide background testimony on the nature of the heart and vascular system, coronary and other arterial diseases and treatments therefor. Such background testimony may include generally the following subjects: the heart and vascular system; coronary heart disease and other arterial diseases; drug therapies related to heart and vascular disease, coronary bypass surgery, angioplasty, stents, requirements of stent design, and problems associated with stent use.

1. The Heart and Vascular System

18. Attached at Tab 2 are diagrams from a book entitled *The Human Body* (Dorling Kindersley 1986), which show the human vascular system depicting vessels such as the aorta and the superior vena cava. There is also a diagram which shows the heart and the various coronary arteries and veins, together with a brief explanation of their function.

2. Coronary Heart Disease and other Arterial Diseases

19. Coronary heart disease is caused by narrowing or blockage of the coronary arteries which supply the heart muscle with blood. Arterial walls have three layers: a very thin inner layer

called the intima, a middle layer called the media which consists of muscle, both maintaining the structural integrity of the artery and allowing it to contract and dilate, and an outer layer called the adventitia, which is a loose layer of connective tissue. These layers can be seen in the diagram at Tab 3. The usual cause of arterial narrowing is atherosclerosis, in which there is a gradual build up of fatty material in the inner layer of the artery wall, followed by deposition of fibrous tissue to produce a plaque which protrudes in to the channel (lumen) of the artery. This narrowing is called a stenosis. As the lumen becomes progressively narrowed, the heart muscle fed by the artery concerned becomes deprived of blood when demands are made of it, for example during exercise. The patient may then complain of angina, which is typically a crushing or constricting sensation in the chest and which may spread elsewhere, for example in the left arm or neck. If the protective fibrous cap on the surface over the fat laden core (the so called atheroma) breaks (there is much on going research into the causes of this break or 'fissure') the platelets in the blood stream adhere to the roughened exposed surface and a blood clot forms. The patient's angina may worsen or suddenly appear at this time (unstable angina). If the lumen of the artery suddenly closes off, blood flow ceases and the heart muscle dies, resulting in a heart attack (myocardial infarction).

20. Arterial disease affects other organs: plaque may accumulate in the carotid arteries to the brain. Small blood clots may form, break off and then travel to vital arteries in the brain causing repeated transient symptoms or a stroke. Patients with leg artery disease may get pain on walking or, usually in the presence of widespread disease, may get threatened limb loss or gangrene.

21. Thus atherosclerosis is a systemic disease which may affect one part of the artery or several. Why it apparently affects one part (at least from the clinical point of view) or even just one artery, is not known, but local factors such as shear stress at branch or bend points in the artery may be important.

22. In addition to trying to stave off the arterial disease by long term attention to so-called risk factors predisposing to the problem, such as cigarette smoking, high cholesterol and diabetes, there are three main ways to treat the symptoms of coronary heart disease and/or improve the blood supply to the heart: drugs, bypass surgery and angioplasty (balloons and/or stents).

3. Drugs

23. Drugs can be used to relieve the symptoms of angina by relaxing the muscle of the artery wall, thus improving blood supply, or making the heart beat less forcefully, thus reducing its workload. Clot dissolving drugs (fibrinolytics) are often used nowadays in the acute phase of a heart attack and 'antiplatelet' drugs (such as aspirin) are given to reduce the tendency of the platelets to stick on plaques, either in the coronary arteries or elsewhere in the arterial system.

4. Coronary Bypass Surgery

24. If a patient's symptoms cannot be controlled by drugs alone and the angiogram (artery x-ray) shows narrowing or blockages of several arteries, the patient may be referred for coronary artery bypass surgery, in which an artery running down the front of the chest on each side (internal mammary artery) and/or superficial veins from the leg are used to bypass the problem by connecting them to the artery beyond the blockage. Coronary artery bypass surgery can relieve angina, quite often for many years if the grafts stay open, and improves life expectancy in some patients with severe disease.

5. Angioplasty

25. Initially developed in the femoral (thigh) arteries by Dr. Charles Dotter in Portland, Oregon, angioplasty consisted of pushing co-axial catheters of progressively increasing diameter through the skin into the femoral artery in the groin under local anaesthetic and, using x-ray screening as guidance, pushing them through the narrowed or blocked section. He reported this

technique of "transluminal dilatation" in 1964 (in his paper entitled "Transluminal Treatment of Arteriosclerotic Obstruction" in *Circulation* Vol. 30. November 1964 p.654-670. a copy of which is at Tab 4. The method was limited by the fact that a channel only as wide as the arterial entry site could be produced. the latter being necessarily limited. Also the technique could not be applied to any other arterial territory remote from the entry site. such as the coronary arteries. because it was known that flexibility would be necessary to negotiate the bends involved. Dotter in his paper did predict eventual application to the coronary vessels.

26. Indeed. after some unsuccessful attempts by several workers (including Dotter himself) to produce a balloon strong enough to dilate an arterial stenosis. Andreas Grüntzig in Zurich developed a catheter with a relatively non-elastic sausage shaped balloon near its tip. The catheter had two channels. one for introducing a guidewire (which could be passed first through the vessel. past the diseased section. so that the balloon catheter could be passed over it and thus be guided to the correct site) and the other channel to inflate the balloon with fluid at high pressure (typically 6 - 12 bar or even higher). After successful work in the peripheral arteries the method was extended to the coronary arteries. initially intraoperatively in San Francisco. in the summer of 1977. Grüntzig performed the first coronary angioplasty by percutaneous means (i.e. through the skin under local anaesthetic in the x-ray catheter lab) in September 1977. and his early experience was reported in the *New England Journal of Medicine* July 12. 1979. Vol 301 No. 2. p61-68 (a copy of which is at Tab 5).

27. Percutaneous transluminal coronary angioplasty is done by passing an outer catheter called a guide catheter through the skin into the arterial system. usually from the femoral artery in the groin or an artery in the arm. Using x-ray screening for guidance. it is then steered to the main coronary artery. Radio-opaque fluid is injected via the catheter. mixing with the blood and flowing

down the artery to reveal the lumen of the vessels and their branches for a few seconds at a time. For angioplasty a fine guidewire (0.014" diameter) is passed through the catheter into the coronary branches. It is steered, again under x-ray control, through the arteries to the diseased portion and beyond. Over this guidewire can then be passed a catheter with a balloon section near its tip, so that the balloon is placed at the site of narrowing. Balloons of varying inflated diameters and lengths are used, typical dimensions being 2.5 - 4mm inflated diameter and 20mm length.

28. This method has the advantages of low morbidity, rapid recovery time and repeatability. It rapidly gained ground in the 80s and 90s (despite some drawbacks described below), such that about 1 million coronary interventional procedures are performed worldwide every year. Over the years, considerable advances have been made with catheters, guide wires and balloons, helping to overcome the technical challenges of the tortuous and/or diseased coronary vessels. An appreciation of the tortuous nature of the vascular system can be seen at Tab 6 together with an example of an actual diseased vessel which can be noted from the angiogram I took. The advances have been made possible by collaboration between industry, and its engineers and the physicians practising the technique. Angioplasty is also in widespread use in the peripheral arteries, in the arteries to the kidneys and to an increasing extent in the carotid arteries supplying the brain.

29. However, vascular balloon dilatation does have some problems. The method involves injury with shearing of the plaque and vessel wall elements relative to each other. This may cause a split ("dissection") to appear in the layers of the artery wall: a false passage or "flap" is thus created which may close off the true lumen. This serious complication often requires emergency surgery. Another problem is that during the weeks or months after the procedure, the artery may re-narrow (restenose). This is partly because the artery as a whole constricts and partly because of excess scar tissue encroaching into the lumen. This causes a return of the patient's problem in about

30 per cent or more of cases.

30. It is because of these drawbacks of angioplasty that various new devices were developed (including lasers and various atherectomy catheters, designed to remove rather than deform the plaque). Another approach was to use stents, which act as a support in the artery. They have to be loaded on a catheter in a collapsed state to allow entry into the arterial entry site and then expanded in some way to the diameter of the artery at the stenosis. Stents are useful because they hold open the layers of the artery wall if there is acute occlusion of the vessel due to the splitting (or "dissection") mentioned earlier, and have thus markedly reduced the risks involved in angioplasty.

31. A patient's progress is monitored by the use of angiograms, i.e., visualisation of the patient's arteries by x-ray contrast. If, having used balloon angioplasty, the artery looks on the angiogram as if it may close off, then stents are often used to prevent the problem. Stents also enable a bigger lumen to be safely achieved during the procedure: even though they are often associated with more scar formation than balloon dilatation alone, the bigger lumen achieved initially will still result in a better lumen later on. Attached at Tab 7 are drawings which show how a stent is intended to work.

32. Transluminal intervention (treatment via the lumen or natural channel of the vessel) using radiological or x-ray techniques is not confined to the arteries and vessels. Many conduits in the body, important for supply or drainage, may become stenosed or blocked by disease of its wall or by compression from without. Examples include the gullet (oesophagus), the airways (trachea and bronchi), the bile ducts and the urinary tract. Problems with all these can be treated in some instances by balloon dilatation and by the technique to be described, stent implantation.

6. Historical Development of Stents

33. Dr. Dotter first proposed that percutaneous transluminal placement of coiled stents

in arteries could be successful. In 1969 in the journal *Investigative Radiology* September - October 1969. Volume 4. Number 5 (a copy of which is at Tab 8) he describes how, having percutaneously introduced an impervious plastic prosthesis, it became apparent that such an impervious prosthesis led to prompt thrombosis (clotting). He thought this could have been due to surface interaction with the blood elements (especially platelets) and/or distortion of blood flow by the prosthesis causing a blood clot to form. This caused him to consider alternatives, so he tested coiled springs. The technique for implanting the prosthesis can be seen from figure 1 in Dr. Dotter's article.

34. Dr. Dotter's experiments were carried out over a period of 2½ years and he was able to show that the use of a coil spring prosthesis allowed the vessel to remain patent for up to that length of time. However, I note from his paper that the coil spring which maintained patency for 2½ years actually migrated on the day of implantation (Dr. Dotter speculated that it might be a result of spasm). This highlights one of two particular problems associated with stenting: migration: another is trauma, i.e. injury to the artery or vessel.

35. As pointed out above, it was Dr. Dotter who conceived of the catheter insertion of intra-arterial scaffolding (although it is widely believed that the term "stent" is derived from splints used in the 19th Century by the London dentist, Charles Stent). The stent used by Dr. Dotter was a helically wound coil made of stainless steel. In later years he used a similar coil but made of nitinol, an alloy made of nickel and titanium. This alloy is described as a "memory metal." In other words, its physical properties are such that it can be fashioned into a particular shape at its "memory" temperature, cooled so that it then effects another shape, but when the "memory" temperature is applied to the metal, it returns to its first shape. A depiction of this stent is at Tab 9.

36. Nitinol coil stents have, in fact been known about since the beginning of the 1980s. A nitinol coil stent was the first stent I actually put into a patient's coronary artery. The problem I

experienced with the nitinol stent was that it could not be heated up sufficiently to ensure it expanded to the optimal diameter. In order to heat the stent, a heated saline solution was passed through the catheter. However, because of the distance the saline solution had to travel, heat loss and the high temperature required to heat up the nitinol coil, it was simply not possible to get enough heat to the stent to cause it to expand properly without incurring significant risk of damage to the vascular system.

37. In 1984 Maass et al (*Radiology* 1984; 152: 659-663, a copy of which is at Tab 10) reported the use of spiral-shaped prostheses made of heat-treated steel alloy, configured as a double helix spiral, torsion-reduced in diameter and transluminally inserted into the vena cava or aorta of dogs or calves. Implantation occurred by releasing the spirals, whereupon they pressed themselves against the vessel wall by elastic expansion.

38. In 1985 Dr. Gianturco and co-workers reported their work with a stent (which became known as the Gianturco stent) made of stainless steel wire and formed in a zig-zig pattern: Radiology 1985; 156; pp.69-72 (a copy of which is at Tab 11). This work was presented at the 70th meeting of the Radiological Society of North America, Washington, November 25-30, 1984 and described the placement of these stents in major vessels of dogs. They were compressed in a Teflon cartridge and advanced through a sheath in the target vessel. On withdrawal of the sheath, the stent was freed and allowed to expand out to the vessel wall.

39. A feature of the Gianturco self-expanding stent is that, once released from its sheath, it will expand until the force of the stent on the walls of the vessel is in equilibrium with the force of the vessel wall on the stent. If, therefore, the Gianturco z-stent is made such that its fully expanded diameter is greater than that of the desired size of the lumen into which it is placed, it may cause undue injury to the vessel.

40. One of the difficulties encountered in placing stents such as the Gianturco z-stent is that the stenosis may be such that expansion of the stent to its full diameter may be prevented. If this occurs, then the interventionist may use a balloon (whether compliant or non-compliant, depending on what he wishes to achieve) in order to expand the stent fully. This technique subsequently became known as the "Swiss Kiss," after Dr. Sigwart used this term when describing his use of it in order to expand a Wallstent fully.

41. As I explain further below, I understand that Dr. Palmaz described and presented his expandable intraluminal graft made of continuous woven stainless steel wire at the 70th Scientific Assembly Annual Meeting of the Radiological Society of North America on 29th November 1984. This is referred to in *Radiology*, 1985; 156; 73-77 (a copy of which is at Tab 12).

42. This stent was produced in two versions: a version made out of soldered wire and a second one made from a slotted tube. Again, as I explain further below, I believe the slotted tube version was also presented at the 29th November 1984 RSNA meeting. The slotted tube version is also described and depicted in the paper by Dr. Palmaz et al entitled "Atherosclerotic Rabbit Aortas: Expandable Intraluminal Grafting". *Radiology*, 1986; 160:723-726 (a copy of which is at Tab 13). In a recent text published in the mid-1990s, Dr. Palmaz himself described the woven stainless steel wire tubular mesh as "intended only for study purposes. The next iteration was a one piece device made of a single material and therefore apt for prosthetic implantation." (*Intravascular Stents: Basic Physical and Biological Properties, in* HANDBOOK OF THE EIGHTH INTERNATIONAL COURSE OF PERIPHERAL VASCULAR INTERVENTION 149-58; at page 150; a copy of which is at Tab 14).

43. Reproduced at Tab 15 is the paper *Implantation of Balloon- Expandable Intravascular Grafts by Catheterisation in Pulmonary Arteries and Systemic Veins* (*Circulation*, Vol. 77, No. 1, January 1988, p 188-199). Drs. Palmaz and Schatz were co-authors. I note, in particular,

the photographs at Fig. 6. From a comparison of the photographs it is apparent that the shape produced upon expansion of the Palmaz stent – whether made by soldering wires together or cutting slots in a tube – looks the same.

44. During 1986 the Palmaz stent became generally known to persons interested in interventional cardiology and radiology. This stent and the Gianturco Roubin I ("GRI"), to which I refer more fully below, were balloon expandable stents and were of interest to those in the field. Such workers were already well aware of the earlier coiled and helix-shaped devices.

45. Throughout the 1980s (and since) information about new methods and devices, including stents, was obtained informally during conversations with colleagues and industry personnel at meetings, and from company representatives visiting hospitals. Publications were of course also a source, but generally by the time publications came out, devices described in them were already subject to discussion by those in the field. There was some cross-information between specialties, for example cardiologists (primarily concerned with coronary angioplasty) and interventional radiologists who performed peripheral vascular procedures and also intervened in the venous system, and other non-vascular tracts. There were (and still are) many meetings and courses attended by those interested in angioplasty techniques and devices. These included specialised courses such as the annual Sheffield Interventional Radiology training course for radiologists, the San Francisco Heart Institute and Atlanta live demonstration courses in coronary angioplasty held every 6 months (at which peripheral and renal artery interventions were also shown) and the major congresses such as the Radiological Society of North America, the American College of Cardiology and the American Heart Association, all of which were and are held annually. One also learned about developments "in the pipeline" from informal conversations with colleagues who had been to such meetings, or similarly from company representatives. Lectures at local or regional level by

interventionists leading the field would also spread such information to others, both those in the field of intervention and other doctors and hospital staff attending the lectures.

46. Also in about 1986 the Wallstent (with which Dr. Ulrich Sigwart is most notably associated) and which was manufactured by Schneider became generally known. The Wallstent is an interwoven self-expanding braided wire mesh stent. It sits on a catheter in unexpanded form with a sheath surrounding it. As the sheath is removed, the wire mesh expands. It is very flexible and does provide some vessel support. However, its closed structure leads to side branch closure and the fact that it shortens on expansion in a rather unpredictable fashion renders it not ideal to use, except in very long segments, for example in stenosed venous bypass grafts.

47. I placed several Wallstents in the femoral (thigh) arteries of patients at the Northern General Hospital in 1988: these all became totally occluded by thrombosis in the first few weeks after implantation.

48. By about the mid 1980's Dr. Roubin, an interventional cardiologist working in Atlanta (having been trained by Grüntzig, who had moved there in 1981), was working with Gianturco in the development of another stent, the Gianturco-Roubin balloon expandable coil stent. Workers in the field, including myself had become aware of this stent by at least 1986. I first saw and handled one in March 1987, when I was a visiting lecturer on the Emory Coronary Angioplasty course and visited the dog lab in which these experimental stents were being assessed. At Tab 16 is a copy of the report I prepared for my colleagues at the Northern General Hospital on my visit, which notes that Gary Roubin was working with a balloon expandable stent. This was the GRI.

49. The GRI stent is a stainless steel length of wire formed into a coil: it is very flexible but had (and still has in my opinion and that of others) the disadvantage of providing poor support to the vessel. A diagram of the GRI is at Tab 17.

50. As reported in the 1985 Palmaz Article, it was apparent that the Palmaz stent suffered from a major limitation, namely, its longitudinal inflexibility. The slotted tube version of the stent (a single tube, 15mm in length), was also not flexible in use. As a result, it could only be used in limited applications, which did not involve a tortuous region of a vessel. In consequence, I believe the stent was shortened to 7 mm. This did not increase its flexibility but, because it was shorter, it could be used in a wider range of applications. Nevertheless, for longer lesions it was not sufficient on its own and a number of stents had to be used together with the attendant problems I discuss below in paragraphs 87 and 88.

51. The Palmaz-Schatz PS153 with a short single bridge, introduced limited flexibility at the articulation points, but at the price of poorer vessel support and associated tissue prolapse. The PS 153 is, in my understanding, the practical implementation of the tubular members and straight connector shown in the '984 and '332 patents.

52. The next introduction in Europe was the spiral Palmaz-Schatz PS154. This was, to my understanding, the practical implementation of what is shown in Figure 10 of the '417 patent. I note that the '417 patent suggests that prior to the development of the device it describes, there was no expandable intraluminal vascular graft for expanding the lumen of a body passageway, which permitted tissue of an elongated section of a body passageway to be supported by an elongated graft, and which provided the necessary flexibility to negotiate the bends and curves in the vascular system. I understand the '417 patent to suggest that the devices shown in Figures 7, 9 and 10 does meet that need.

53. As with the original Palmaz stent, the Palmaz-Schatz PS 154 can be bent if sufficient force is applied to it, and to that extent, it does have a limited flexibility. But for practical purposes, and as with the original Palmaz stent, it was not in my experience flexible. It did not have sufficient

flexibility to negotiate the bends and curves of the vascular system. In my view, in terms of flexibility, the spiral Palmaz-Schatz is far less flexible than the Palmaz-Schatz PS 153 articulated by a single bridge. The PS 154 was never commercially introduced in the United States.

54. The 1990s saw the introduction of various new stents, the first of which was the ACS Multi-Link. A diagram of the Multi-Link is at Tab 18. It is a series of corrugated rings joined together by three metal bridges separated by 120 degrees on the circumference of the ring. The ACS Multi-Link stent was introduced in the United States market in October, 1997.

55. Another linked stent is the AVE GFX stent, the basic structure of which is a series of sinusoidal rings. A diagram of the AVE GFX is at Tab 19. This was first available for clinical use in Europe in 1994, and received FDA approval in the United States in December, 1997.

56. Variations of coiled stents have also been developed. At Tab 20 is a depiction of the Wiktor stent. I believe that animal work on the Wiktor stent was performed in 1987 and the first human implantation was in 1990. Other examples of coiled stents are the GR II (based on the original GRI design, but with some alterations designed to increase vessel support and help maintain integrity of the stent) and the Cordis/Johnson & Johnson Crossflex stent. In my opinion, these stents do give somewhat better vessel support than the early GRI stent, but they still err on the side of reduced support for the sake of maintaining flexibility.

57. I became aware of the NIR stent in 1995. I believe that the NIR stent with its multi-cellular geometry is a fundamentally different design both to the Palmaz and Palmaz Schatz stents, and the Multi-Link sent. In this respect, it can be fully regarded as the start of a new generation of stents. The NIR stent achieves flexibility during delivery, and yet achieves good support of the vessel after deployment, by changing its geometry. This enables each cell to elongate or foreshorten, depending on its position as it tracks through the curvature of the vessels, the various regions of the

cells moving relative to each other. As the stent is expanded, the U-shaped loops, which are initially at an angle relative to one another, tend to align providing increased radial strength.

58. Following the introduction of the NIR stent, other stents have been introduced seeking to provide the combination of flexibility without articulation and support after expansion. Examples are the BeStent and the Cordis/Johnson & Johnson Crown stent. At Tab 21 is a depiction of the BeStent. The BeStent has serpentine radial and longitudinal struts which cross each other: animal work was done in 1995 and clinical use commenced in 1996. At Tab 22 is a depiction of the Crown stent. It is configured in a sinusoidal fashion with no designated articulation points. I believe this is claimed to provide "greatly increased longitudinal flexibility" and also better side-branch access than the previous Palmaz Schatz stent.

7. Stents - Ideal Properties

59. It is my belief that even in the early days, it was appreciated that there were a number of ideal properties of a stent:

a. *Deliverability (flexibility and trackability):*

This feature is necessary for manoeuvring the stent and its delivery system around bends in the guide catheter and the coronary vessels. The bends can be seen on the angiogram at Tab 6. The coronary vessels always bend to some degree, sometimes markedly so. Also, a feature of deliverability is the system's capacity to be provided with a low profile to allow passage through the guide catheter and vessels to the desired site. A further feature is that if the stent is too rigid it may, during delivery to the stenosed site, cause the vessel to kink or damage the vessel wall. In my experience, in some instances, it has not been possible to deliver rigid stents at all (particularly the Palmaz stent). Without flexibility and trackability, injury to the

vessel wall can occur as the stent, mounted on a catheter, is manoeuvred through the vessel. This may cause an acute complication, and may be relevant to in-stent restenosis.

b. *Strength and coverage:*

A stent must have a minimum tendency to recoil, and be strong enough to withstand the radial forces upon it caused by the vessel wall and/or plaque. There must be sufficient metal coverage of the wall to prevent intrusion of plaque, intimal flaps or other vessel wall constituents into the lumen.

c. *Thrombo-resistance:*

It was realised at an early stage that attraction of blood proteins and platelets to the stent's surface would be undesirable. Relevant to this is the configuration of the stent and its effect on blood flow, and the haemocompatibility of its surface.

d. *Biocompatibility:*

By this is meant minimisation of tissue reaction, e.g. inflammation, caused by the stent material which would eventually result in excess tissue growth associated with the stent and therefore re-narrowing of the vessel lumen.

e. *Radiographic visibility:*

The easier the stent can be seen on x-ray screening, the easier it is to place accurately at the desired site. This can be particularly important when implanting short stents and multiple stents so that they can be very precisely positioned. On the other hand, if the stent is too radio dense, it can obscure detail of the vessel lumen when x-ray contrast material is injected.

f. *Good expansion range:*

As indicated above, the stent should be of as narrow a diameter as possible for delivery, and then be capable of reliable expansion over a range of vessel diameters with maintained structural integrity.

g. *Lack of side branch compromise:*

Particularly in the coronary vessels important side branches are common and are not infrequently associated with lesions requiring stenting. A minimum degree of compromise to such side branches by the stent struts was recognised as desirable.

h. *Conformance to anatomy:*

If the stent is too rigid after deployment it may unduly straighten the vessels. Particularly in the coronary arteries, which are in constant motion, this may cause tissue injury at either end of the stent.

60. Thus if a stent is to be "ideal", it has to have the ability to negotiate the most tortuous of vessels. This is partly what is meant by the term "deliverability." Other than the coil spring stents and the Wallstent, other stents did not have sufficient flexibility. However, the coil springs and Wallstent suffer from other problems, making them less than ideal.

61. Strength in the radial direction is important, but to achieve it, until the introduction of the stents of the 1990s, such as the NIR stent, it had not been possible to obtain a stent with longitudinal flexibility and which ultimately provides the necessary radial strength.

8. Problems Associated With Stents

62. I have referred above to certain defects and problems associated with the various known stents. There will be situations where one type of stent is better suited than another to solving the particular problem faced by the interventional cardiologist. For example, it may be that the lesion is in an area which is tortuous to get to, and all that is needed is to hold an intimal flap against

the artery wall, which takes little radial force. In this situation (absent the more recent stent designs described above) the helical coil stent would be a suitable choice, particularly if the occluded areas are relatively long. On the other hand some lesions are resistant, and a strong supportive stent is needed. This can apply to the coronary arteries or to larger vessels such as the common iliac artery or superior vena cava. Either of the Gianturco stent or the Palmaz or Palmaz-Schatz stents might be suitable in these cases if the anatomy were otherwise favourable. The Palmaz stent would only be suitable for short segments because of its inflexibility. In the coronary setting, the NIR would be suitable in all these cases because of its mechanical characteristics and since it is available in large enough sizes.

63. To some extent, what an interventional cardiologist uses depends on what is available to him at the time. In practice, this is often governed by the currently least expensive one available. However, because of the variety of situations which may be present, some of them unpredictable, it is preferable to have a variety of stents on hand. For example at the Northern General Hospital the following are available: the NIR by BSC/Scimed; the BiodivYsio by Biocompatibles; the Wallstent by BSC Scimed; the Multilink Duet by ACS; the Seaquence by Nycomed; the GFX (and its successors the S670 and S540) by AVE; and the Gianturco Roubin II by Cook. Most of these are sold either mounted or already crimped on to a balloon catheter; one exception is the Wallstent which is self expanding and comes with its own special sheath system.

B. Person of Ordinary Skill in the Art

64. A "person" of ordinary skill in the art during the mid-1980s would have comprised a person or persons with the knowledge and skills of (i) a physician specializing in radiology, cardiology, cardiovascular surgery, or some related discipline, and (ii) an engineer having at least a bachelor's degree in mechanical or biomedical engineering or materials science, and experience in the design of implantable medical devices. The physician member of the stent design team of ordinary skill during the relevant time period would have possessed at least the following knowledge:

a. currency with relevant literature;

b. experience with vascular disease and other luminal stenoses;

c. familiarity of balloon angioplasty and its shortcomings;

d. awareness of stents as a possible solution to restenosis and acute closure; and

e. knowledge of the limitations placed on device design by the anatomy and physiology of the human body.

65. My opinion is based upon my knowledge and experience with the process by which medical devices used in interventional radiology and cardiology, such as catheters and stents, have generally been designed, both currently and during the mid-1980s. Interventional physicians and surgeons have professional contacts and relationships with engineers employed by medical device manufacturers and engineering faculty at universities involved in biomedical research. Medical device manufacturers send engineers to professional medical meetings, such as the annual meeting of the Radiological Society of North America (RSNA), the Congress of the American College of Cardiology, and the many live demonstration courses which have regularly taken place since the advent of angioplasty. Physicians serve on the medical advisory boards of medical device

manufacturers and enter into consulting agreements with medical device manufacturers. Interventional physicians who teach at medical schools develop cooperative research relationships with academics at engineering schools. In the course of these relationships, a design concept for a device can originate either from the physicians or the engineers, but each group needs the other to develop the design to the stage of performing clinical trials.

C. Obviousness of Claims 23, 44, 51 and 52 of the '762 Patent[1]

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[1] The text of those claims (including claim 13, on which claim 23 depends) reads as follows:

13. An expandable intraluminal vascular graft, comprising:

a thin-walled tubular member having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member into a body passageway having a lumen; and

the tubular member having a second, expanded and deformed diameter, upon the application from the interior of the tubular member of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the lumen of the body passageway.

23. The expandable intraluminal vascular graft of claim 13, wherein the outside of the wall surface of the tubular member is a smooth surface, when the tubular member has the first diameter.

44. A method for implanting a balloon expandable stent prosthesis within a passageway of a coronary artery having an area of stenosis, comprising the steps of:

utilizing a thin-walled, tubular member as the stent prosthesis, the tubular member having a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

disposing the stent prosthesis upon a catheter having an inflatable balloon portion;

inserting the stent prosthesis and catheter within the passageway by percutaneous catheterization;

delivering the catheter and stent prosthesis to the area of stenosis without surgically exposing the area of the passageway; and

expanding and deforming the stent prosthesis at the area of stenosis within the coronary artery passageway by expanding the inflatable balloon portion of the catheter associated with the stent prosthesis to force the stent prosthesis radially outwardly into contact with the area of stenosis in

(continued...)

1. 1984 Palmaz Abstract and the Wallsten Patent

66. The 1984 Palmaz Abstract (Tab 23) describes a tubular mesh device to provide support and prevent recoil and restenosis following angioplasty. It is apparent that the mesh is balloon-expandable, rather than self-expanding, given the description that the tubular mesh has "soldered cross points," which precludes a self-expanding tubular mesh, such as that described in the Wallsten patent (Tab 24).[2] Moreover, the balloon-expanded tubular mesh is necessarily plastically deformed by the balloon, since the expanded tubular mesh is to function as "a supportive endoprosthesis to prevent recoil of the arterial wall." Thus, the 1984 Palmaz Abstract teaches the

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[1](...continued)
the passageway, the stent prosthesis being controllably deformed beyond its elastic limit.

51. In combination, a balloon expandable stent prosthesis for implantation in the passageway of a coronary artery having an area of stenosis and a catheter, comprising:

an expandable stent prosthesis being a thin-walled tubular member having first and second ends and a wall having an outer wall surface disposed between the first and second ends, the wall having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of the tubular member;

a catheter having an expandable, inflatable balloon portion;

the tubular member being disposed on the balloon portion of the catheter;

the tubular member having a first diameter which permits intraluminal delivery of the tubular member and the catheter into a lumen of a coronary artery having an area of stenosis and wherein the outside of the wall surface of the tubular member is a smooth surface when the tubular member has the first diameter; and

the tubular member having a second, expanded and deformed diameter upon the application from the interior of the tubular member of radially, outwardly extending force, by inflating the balloon portion of the catheter, which second diameter is variable and controlled by the amount of force applied to the tubular member, whereby the tubular member may be expanded and deformed to expand the coronary artery in the area of stenosis.

52. The combination of claim 51, wherein at least certain of the slots are defined by a pair of spaced apart elongate members that are connected togther at one end of each of the elongate members so as to define an open ended slot.

[2] I am aware that during the reexamination of the parent '665 patent the Examiner took a different view, but he may have misunderstood the nature of the welding described in the Wallsten patent.

basic concept of a balloon-expandable stent, which is: (1) delivered to the treatment site by balloon catheter in a smaller, unexpanded state, (2) expanded by the balloon's application of a force to the interior of the stent, plastically deforming it to a larger, expanded diameter, and (3) leaving the deformed stent in the body in order to support the treatment site. In addition, the 1984 Palmaz Abstract discloses in some detail the structure of a balloon expandable stent like that shown in the '665 patent. While the 1984 Palmaz Abstract does not contain any illustration, a person of ordinary skill in the art with the Wallsten patent before him would have no trouble understanding the nature of the tubular mesh design. The Wallsten patent illustrates an example of a tubular mesh in the very same field of stents.

67. I do not believe that the typographical errors that appear in the published 1984 Palmaz Abstract would have prevented a person of ordinary skill in the art from understanding the device described. Specifically, the description of the grafts as "six, eight, and 10 ml in diameter by 20 ml in length" would have readily been understood as describing those dimensions in millimeters. In addition, I understand that the reference to the graft's wall thickness as "20-45 microns" is an error, and that the true approximate thickness of the grafts described was 200-450 microns. It is my opinion nonetheless that a person of ordinary skill in the art would have understood the structure of the graft described.

68. I believe that a number of things would have been readily apparent about such a device at the time. First, even though wire might be of uniform cross-section, at the points where the wire intersected there would be a double thickness. In fact, the thickness might be slightly more than double by virtue of the solder or other material used to fix the wires together. Such double thickness would be likely to produce an irregular surface on implantation, which in turn would be likely to cause turbulent blood flow around the wires. Interference with blood flow is something that one

would have been concerned would cause platelet aggregation and thrombosis. This phenomenon was well known from experience of blood flow over guidewires and was known to be liable to cause thrombosis.

69. Second. I believe that one would have a concern using a second metal to secure the wires together. Even small electrolytic effects were thought to be a potential cause of thrombosis.

70. Third. I would be very concerned that any possibility of failure at a joint upon expansion of the device might lead to weakening of the structure and/or damage to the balloon. I would be concerned that a structure involving cross-wires secured in this way might fail at least at some points on expansion at high pressure in the artery.

71. In the light of these matters I believe that by looking at such a structure involving cross wires it would be readily apparent that a potential way of dealing with my concerns would be to make the device in a one piece manner out of a slotted tube. This would enable the benefits of the device to be retained while avoiding the double thickness and other problems referred to above. Such a one-piece device would be capable of variable expansion. depending on the final diameter of the expanded balloon.

72. I am reinforced in my view having read the article by Dr. Palmaz and Dr. Reuter published in the Handbook of the Eighth International Course of Peripheral Vascular Intervention. a copy of which article is at Tab 14. In that article Dr. Palmaz states that the wire design was intended only for study purposes and that the slotted tube device made from one single piece of material was "apt for prosthetic implantation" and the next "iteration" from the wire mesh design.

2. Ersek

73. One such example of a once-piece wire-mesh-type design is described in the Ersek

patent (attached at Tab 25), from the related field of vascular surgery.[3]

74. Ersek describes a deformable sleeve secured in place by expansion. This is claimed to provide controlled, dependable expansion and to fix grafts quicker than by conventional methods of suturing. It therefore teaches implantation and automatic fixation of a porous device made of stainless steel or other material. It is stated that the device can be modular and one module connected to another module by wires. It is intended as a fixation device, but would have been suitable as a graft in some vessels as it would clearly be capable of supporting the vessel wall.

75. From Figure 1 of Ersek and lines 14 to 28, I understand that Ersek is seeking to fix the artificial graft in place of a severed aorta. From the diagram it is apparent that the Ersek invention (described as a fixation sleeve - column 1, line 64) is at least in part expanded against the aortic wall so that it is partly in the aorta and partly in the graft.

76. The importance of this is described at column 2, line 56 until line 75. The inventor here has clearly appreciated that the tubular sleeve of his invention must be of a deformable material but that the material must be non-toxic such as stainless steel. He has also appreciated the desire to have an open area (formed once the metal sheet with the staggered parallel slits has been expanded) which allows coverage of the device with cells that normally line the artery. It is also apparent that part of the device which is against the vessel wall is supporting that vessel wall – exactly the function of an intraluminal vascular graft.

77. Ersek's patent suggests that the sheet with slits is then stretched (the degree is not specifically stated) to open the slits and to expand the metal sheet in a direction perpendicular to the longitudinal axis of the slits themselves, so that they become diamond-like apertures.

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[3] I note that Palmaz himself published both in journals in the field of interventional radiology and cardiology, as well as the journal *Surgery*.

78. At line 6, column 3, the degree of stretch is perhaps indicated by the suggestion that the members 22 extend generally longitudinally. In other words, it has not been expanded to the fullest extent of the "diamond". The sheet is then spot welded to form a tubular sleeve. At line 14 in column 3 it states that the tubular sleeve may "easily be expanded by about 50 per cent beyond its original diameter." In Ersek's tubular sleeve the twist in the ribbon-like members (22) causes them to protrude into the vessel lining. This in turn, it is suggested, encourages the lining to proliferate through the open lattice work of the tubular sleeve, with the result that there is little metal coming into contact with the blood stream itself.

79. A method described for expanding the tubular sleeve is illustrated in figures 6 and 7. Essentially, the resilient rings 35 of the expansion tool are compressed so that they expand radially thereby expanding the tubular sleeve in an outwardly, radial manner.

80. I believe that anyone interested in making a tubular stent and having read Ersek would appreciate it could be used as a stent for some applications and, if made in a smaller size, could be used for many applications. The device as described would be useful as an intraluminal vascular graft. It comprises a tubular member, formed by a series of intersecting elongate members. Such a device is expandable, and the degree of expansion determined by an outwardly extending force, such that the varied diameter would be controlled by the amount of force applied. I believe that it would also be apparent that such a device could be cut from a pre-existing tube.

81. Further it would have been readily apparent that the tube could be cut as shown in Figure 1A of the '762 patent. If cut from a sheet or tube then the resultant device would comprise struts having a regular, uniform rectangular cross-section. Such a device would have the appearance of Figure 1A and, upon expansion, Figure 1B.

82. Although I understand that there is some question with respect to the proper

construction to be accorded the term "smooth" as used in the '762 patent, it is nonetheless clear that in the field of percutaneous, intraluminal vascular intervention, a person of ordinary skill in the art would have understood that a balloon-delivered graft must be smooth before expansion, in contrast to the rough texture described as preferable by Ersek for use as a fixation device in the vascular surgery setting.

3. Hammerslag

83. The Hammerslag patent (attached at Tab 26) further describes the principle of a balloon-expandable, intraluminally delivered, implantable device. The tubular liner is placed on a balloon catheter, moved through the arterial system to the delivery site, and then deployed by inflation of the balloon at the delivery site.

84. If a person of ordinary skill in the art entertained any doubts about the operation of a balloon-delivered, balloon-expandable stent after his review of the 1984 Palmaz Abstract, the Wallsten patent, and the Ersek patent, such doubt would be eliminated on review of the Hammerslag patent.

4. Additional Prior Art as of November 3, 1986

85. If the priority date of the '762 patent is deemed to be November 3, 1986, there is additional prior art that confirms my conclusions:

a. As described above in connection with the 1984 Palmaz Abstract, the April 1985 Palmaz Abstract (attached at Tab 27) also describes a balloon-mounted, balloon-expandable tubular wire mesh used as an intraluminal graft. It describes the tubular mesh as having "a wall thickness of 0.2 - 0.4 mm."

b. Further, the 1985 Palmaz Article (Tab 12) and the Second 1985 Palmaz Article (attached at Tab 28) describe in further detail the construction of the tubular wire

mesh graft, and provide diagrams of that wire mesh tube.

D. Obviousness of Claims 17, 18, 25 and 26 of the '417 Patent

1. 1985 Palmaz Article and Earlier Palmaz Patents

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[4] The text of those claims reads as follows:

17. A method for expanding the lumen of a body passageway comprising the steps of:

connecting a plurality of intraluminal grafts by at least one flexible connector member disposed between adjacent grafts:

inserting the plurality of connected intraluminal grafts, disposed upon a catheter, into the body passageway until the grafts are disposed adjacent a desired location within the body passageway; and

expanding a portion of the catheter to provide controllable expansion of the intraluminal grafts radially, outwardly into contact with the body passageway, by deforming a portion of the intraluminal grafts with a force in excess of the elastic limit of the portion of the intraluminal grafts, until the lumen of the body passageway at the desired location in the body passageway has been expanded, whereby the intraluminal grafts prevent the body passageway from collapsing and decreasing the size of the expanded lumen, and the intraluminal rafts remain in the passageway.

18. The method of claim 17, including the step of disposing the at least one connector member in a non-parallel relationship with respect to the longitudinal axis of the intraluminal grafts.

25. An expandable intraluminal vascular graft, comprising:

a plurality of thin-walled tubular members, each having first and second ends and a wall surface disposed between the first and second ends, the wall surface having a substantially uniform thickness and a plurality of slots formed therein, the slots being disposed substantially parallel to the longitudinal axis of each tubular member;

at least one connector member being disposed between adjacent tubular members to flexibly connect adjacent tubular members:

each tubular member having a first diameter which permits intraluminal delivery of the tubular members into a body passageway having a lumen; and

the tubular members having a second, expanded and deformed diameter, upon the application from the interior of the tubular members of a radially, outwardly extending force, which second diameter is variable and dependent upon the amount of force applied to the tubular members, whereby the tubular members may be expanded and deformed to expand the lumen of the body passageway.

26. The expandable intraluminal graft of claim 25, wherein at least one connector member is disposed in a non-parallel relationship with respect to the longitudinal axis of the tubular members.

86. As described above, it was readily apparent that the wire mesh tubes described in the 1984 Palmaz Abstract and the '665 and '762 patents had very limited flexibility. On page 76 of the 1985 Palmaz Article (Tab 12), the authors recognise that "the lack of longitudinal flexibility" is one of the disadvantages inherent in the wire mesh version of the Palmaz graft, as described in that paper and shown in Figs. 1A and 1B of the '665 patent. What this means is that because of the lack of flexibility it may either be impossible to reach the area of the lesion or kinking of the artery may occur causing damage or immediate thrombosis.

87. The authors in the 1985 Palmaz Article say that the flexibility problem "was later solved by using shorter grafts or grafts in tandem." Indeed, to aid delivery, the Palmaz stent was shortened to 7mm in length so that separate stents could be placed on a balloon, or multiple stents separately implanted. Neither of these arrangements was satisfactory. Multiple stents on one balloon carried the risk of displacement off the balloon with resultant embolisation (i.e. migration) of the stent to other arterial territories. Movement of the stents relative to each other during passage to the lesion or during implantation resulted in either excessive overlap or an excessive gap between the stents, neither of which was regarded as desirable. The placement of separate 7mm stents is a time consuming exercise requiring very precise implantation (particularly difficult with a stent which is hardly radio-opaque at all) and subjects the vessel at and near the lesion to greater trauma by the methods of implantation.

88. By March 1988, I believe that anyone interested in stents who read the 1985 Palmaz Article would have been aware of the wire mesh stent as well as the slotted tube version depicted in the '762 patent.[5] Those reading the 1985 Palmaz Article would note that it suggests using grafts

[5] Moreover, I am advised that the '665 and '762 patents can be treated as prior art in any event because they were filed earlier and have a different inventive entity.

in tandem. To the extent that the grafts were used in tandem but not connected to each other, there would, I believe, be a significant risk of migration of the grafts relative to each other during delivery. In addition, as described above, the serial placement of multiple stents is a time consuming and difficult exercise requiring very precise implantation, which subjects the vessel at and near the lesion to greater trauma.

89. A simple and plain solution to these problems was to join the stents together with a single strut as a flexible connector, in order to allow flexibility of the individual stents to enable the whole device to negotiate the bends in the vascular system. Such a device was in fact introduced. The disadvantage of this single bridge was that it caused a gap between the stents allowing recoil of the vessel and/or prolapse of the vessel wall constituents.

90. I believe another obvious way of connecting the stents would have been to put in a coiled connector because coil-shaped stents or prostheses were already known about in the field and because it was clearly necessary to provide a flexible connector, providing at least some wall coverage, and one that would be capable of radial expansion.

91. I think it was self-evident to place a connector in the plane of the prosthetic device (as I believe that term is used in that patent) so that the connector would not protrude into the lumen. The benefits of this arrangement would apply both before deployment, during negotiation to the stenosis and after deployment of the prosthesis.

92. My conclusions on the obviousness of connecting stents in tandem together is further supported by a number of additional articles by others.

2. Wallace et al.: First Wire Strut Article

93. The Wallace et al. paper attached at Tab 29 (and I note that Dr. Gianturco was a co-author) shows the use of two Gianturco z-stents connected by a wire strut. The Gianturco z-stents

were constructed of stainless steel wire bent in a zig-zag configuration to form a cylinder. As explained above, these stents are compressed, placed on a catheter and then covered by a sheath. Once the catheter is inserted and reaches the relevant occluded site, the sheath is withdrawn allowing the Gianturco z-stent to expand. As I have pointed out above and refer to further below, these stents could also be further expanded by a balloon catheter.

94. The article explains that the stents were either used individually or that two stents were connected by a wire strut and inserted together. It is apparent from Fig. 3 that the stents in A and B are not immediately behind one another as is the case in Fig. 2 but are offset, most likely as a result of the shape of the vessel into which the stents have been placed. This shows that the bridge, whilst at the same time preventing migration of the two stents, has also allowed them to be flexible relative to one another. Although not entirely clear from the photographs, this could either be because of flexing by the stent at the junction of the stent and the metal bridge, or because the bridge itself flexes, or a combination of the two.

95. If, for any reason, it was not apparent that two Palmaz stents could be connected by means of a metal bridge, I believe it would have been apparent in the light of this article or to anyone aware of these connected Gianturco z-stents.

3. Charnsangavej et al.: The Second Wire Strut Article

96. This is another paper (attached at Tab 30) published in 1986 by a team including Dr. Gianturco. It describes the placing of Gianturco stents into dogs and patients.

97. Figure 1 shows at (a) a Gianturco and at (b) a double stent. The text indicates that the two stents were connected by a wire strut, the combination allowing a greater expansile force than a single long stent and better stabilisation during release. Looking at Figure 1(b) it is apparent that the wire strut has provided a measure of flexibility at the connection. The two stents are slightly

displaced relative to each other.

4. Rösch Articles: The First and Second Monofilament Articles

98. Rösch's First Monofilament Article (attached at Tab 31) describes stents used in combination, particularly a stent body with one or two wire skirts. These elements were connected by monofilament lines. Such a connection would have been understood to be flexible.

99. Rösch's Second Monofilament Article (attached at Tab 32), written for the meeting of the Society of Cardiovascular and Interventional Radiology, March 23-26, 1987, describes the use of two or more stents "connected by a wire strut or monofilament line to form a stent combination." The authors note that balloon catheters can be used to augment the delivery of z-stents.

5. Connector Design

100. In respect of claims 17 and 25, I believe it was obvious that such a connector should be in the plane of individual tubular members and could be oriented in a position which was not parallel to the axis of the tubular member. If more than one connector were to be used, for example to reduce the bare area between the stents, in an attempt to maintain flexibility and to allow some relative angular movement during delivery, it would be obvious to make such multiple connectors nonparallel to the longitudinal axis of the stent.

101. My conclusions can also be further supported by additional articles, including:

a. Josef Rösch et al., *Modified Gianturco Expandable Wire Stents in Experimental and Clinical Use*, 31 ANNALES DE RADIOLOGIE 100-03 (1988) (presented at CIRSE meeting, Porto Cervo, Sardinia, May 25-29, 1987) (attached at Tab 33);

b. Lawrence et al., *Percutaneous Endovascular Graft: Experimental Evaluation*, 163 RADIOLOGY 357 (May 1987) (attached at Tab 34);

c. Josef Rösch et al., *Gianturco Expandable Wire Stents in the Treatment of*

Superior Vena Cava Syndrome Recurring After Maximum-Tolerance Radiation, 60 CANCER 1243-46 (Sept. 1987) (attached at Tab 35);

d. Chusilp Charnsangavej et al., *A New Expandable Metallic Stent For Dilatation of Stenotic Tubular Structures: Experimental and Clinical Evaluation*, 3 HOUSTON MEDICAL JOURNAL 41-51 (June 1987) (attached at Tab 36).

E. Obviousness of Claims 22 and 24 of the '332 Patent[6]

102. For the same reasons described above in connection with the '417 patent, the subject

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[6] The text of those claims reads as follows:

22. A balloon expandable coronary stent for delivery to a coronary artery through an access artery, the stent comprising:

at least two segments, each segment having a generally tubular shape and a first end and a second end;

each segment having a plurality of openings that are disposed substantially parallel to the longitudinal axis of the segment, the openings forming a series of alternating open and closed portions in each of the first and second ends of the segment;

the segments being arranged so that at least one closed portion of the second end of a first segment is in longitudinal alignment with a closed portion of the first end of a second segment;

a connector extending between and connecting the aligned closed portion of the second end of the first segment to the aligned closed portion of the first end of the second segment, the connector being an elongate flexible member that extends between and is integrally formed with the aligned closed portions;

whereby each of the segments may be displaced at an angle with respect to the longitudinal axis of an adjacent segment when the stent is delivered through a curved portion of the access or coronary arteries; and

the stent having a first diameter which permits intraluminal delivery of the stent through the access artery by percutaneous catheterization and a second, expanded and deformed diameter, the second diameter being attained upon the application from the interior of the stent of a radially, outwardly directed force by inflating a balloon, which second diameter is variable and dependent upon the amount of force applied to the stent, whereby the stent may be expanded and deformed beyond its elastic limit to expand the lumen of the coronary artery.

24. The stent of claim 22 wherein each of the segments include at least one cylindrical element formed from a plurality of struts so as to define the open and closed portions.

matter of claims 22 and 24 of the '332 patent would have been obvious to a person of ordinary skill in the art as of October 4, 1988.

103. In addition, the '417 patent, which I also understand to be prior art to the '332 patent, expressly describes the concept of a segmented stent with the segments joined by a flexible connector.

104. Although claim 22 uses terminology different from that in the specification of the '332 patent, the only significant distinction between that language and the structure disclosed in the '417 patent is the additional requirement that the connector attaches two closed portions aligned along the longitudinal axis of the stent. That additional requirement is plainly obvious: indeed, the language of claim 22 describes the simplest, most direct connector one could imagine in order to connect adjacent tubular members of the type described in the '417 patent.

105. With respect to claim 24, whatever part of the stent is intended to be described by the new term "cylindrical element," it must be the same cylindrically shaped segments shown in the '665, '762, and '417 patents, because nothing else is disclosed in the description of the '332 patent.

F. Disclosure of the '332 Patent

106. Finally, there is no disclosure of having multiple connectors in the specification of the '332 patent, nor is there any connector described other than a single, straight connector. Since it is apparent that the use of more than one straight connector to connect two stents actually reduces the freedom of movement of each stent relative to one another, if more than two are used, it is necessary to orient them at an angle to the longitudinal axis of the stent. Otherwise, any flexibility would be reduced or lost altogether. However, unlike the '417 patent, which shows multiple connectors so arranged, the '984 and '332 patents show only one connector between adjacent stents; no arrangement is shown with more than one connector. Nor is there any description of how the

connectors must be arranged if one chooses to use more than one connector.

V. EXHIBITS TO BE USED

107. The exhibits to be used include the various items referred to above, as well as diagrams, models, or photographs of the structures described in those items. I may also rely on demonstrative exhibits and summaries that have not yet been prepared.

VI. PUBLICATIONS I HAVE AUTHORED

108. See the list attached to my curriculum vitae.

VII. COMPENSATION

109. I receive $450.00 per hour (and $225.00 per hour for travel time).

VIII. INVOLVEMENT IN OTHER CASES

110. I have testified in the following cases in the past four years:

a. *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, C.A. No. IP 98-1108 C. H/G (S.D.In.);

b. *Johnson & Johnson Interventional Systems, Co. v. Cook Inc.* (C.A. IP95-1262-C-T G); and

c. *Boston Scientific Ltd. v. Palmaz*, CH 1997 B. Nos. 1495, 1496, 1493, 1497 (U.K. Ch. Div., Patents Ct.).

IX. SUPPLEMENTATION

I may supplement this report if I become aware of additional pertinent information or in response to the testimony of others. Moreover, I may comment on or testify in response to the testimony of other witnesses, including witnesses who testify on behalf of plaintiffs.

Dated 24 January 2000

David C. Cumberland

DAVID C. CUMBERLAND, M.D.

EXHIBIT C

United States Patent

Ersek

[15] **3,657,744**

[45] **Apr. 25, 1972**

[54] METHOD FOR FIXING PROSTHETIC IMPLANTS IN A LIVING BODY

[72] Inventor: **Robert A. Ersek, St. Louis Park, Minn.**

[73] Assignee: **The Regents of the University of Minnesota, Minneapolis, Minn.**

[22] Filed: **May 8, 1970**

[21] Appl. No.: **35,815**

[52] **U.S. Cl.**.....**3/1, 3/DIG. 1, 3/DIG. 3, 128/334 R**

[51] **Int. Cl.**.....**A61f 1/22, A61f 1/24**

[58] **Field of Search**.....**128/334 R, 334 C, 341, 343, 128/348; 3/1, DIG. 1, DIG. 3**

[56] **References Cited**

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3,509,883	5/1970	Dibelius	128/348
3,221,746	12/1965	Noble	128/334 R

FOREIGN PATENTS OR APPLICATIONS

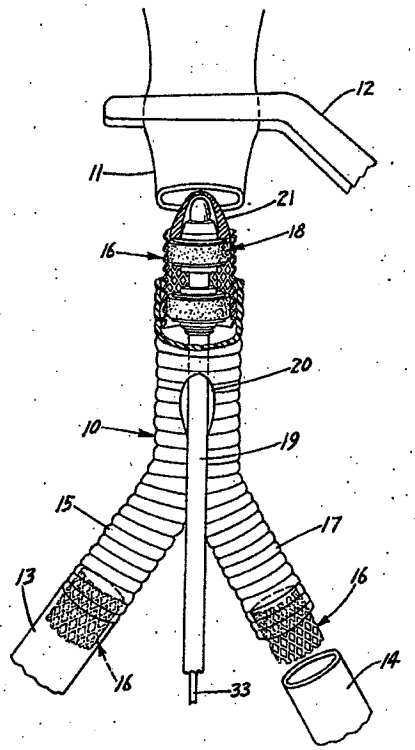
180,750	9/1966	U.S.S.R.	3/DIG. 3

Primary Examiner—Richard A. Gaudet
Assistant Examiner—Ronald L. Frinks
Attorney—Burd, Braddock & Bartz

[57] **ABSTRACT**

A device and method for facilitating the rapid positive fixation of implanted prosthetic members in a living body. The device comprises a tubular sleeve of deformable material to which the prosthetic member is secured and which is capable of being expanded radially into intimate engagement with surrounding tissue. The fixation device and prosthetic member, such as heart valve, vessel graft, etc., are prepared by assembly prior to surgery. The assembly may be rapidly introduced into the transplant situs during surgery and secured in place by expansion of the deformable sleeve by use of an expansion tool.

3 Claims, 9 Drawing Figures



PATENTED APR 25 1972 3,657,744

SHEET 1 OF 2

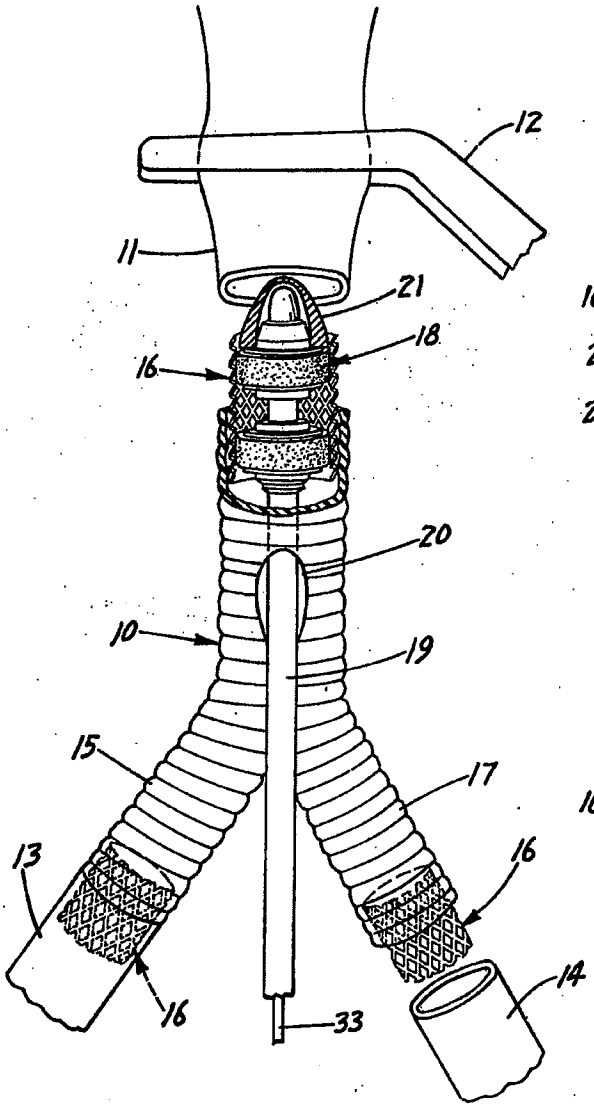


FIG. 1

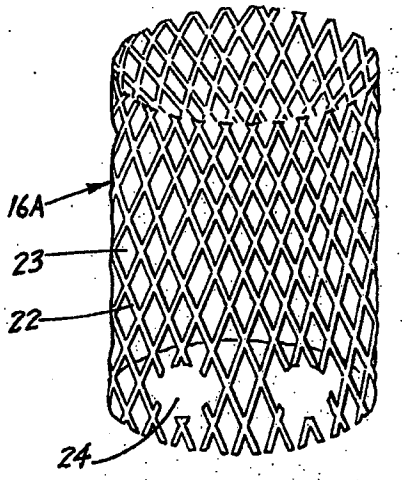


FIG. 2

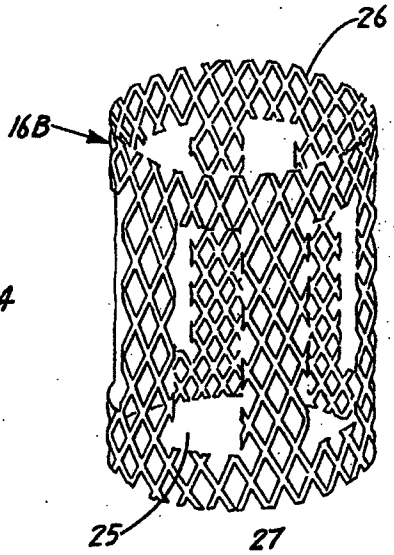


FIG. 3

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PATENTED APR 25 1972 3,657,744

SHEET 2 OF 2

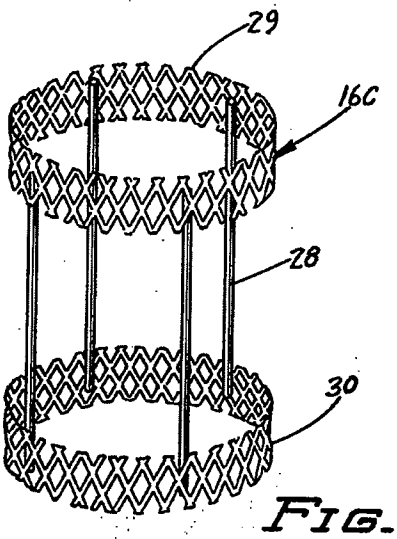

FIG. 4

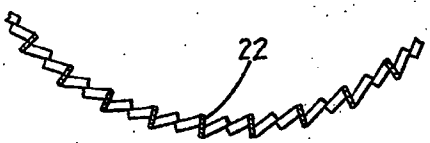

FIG. 5

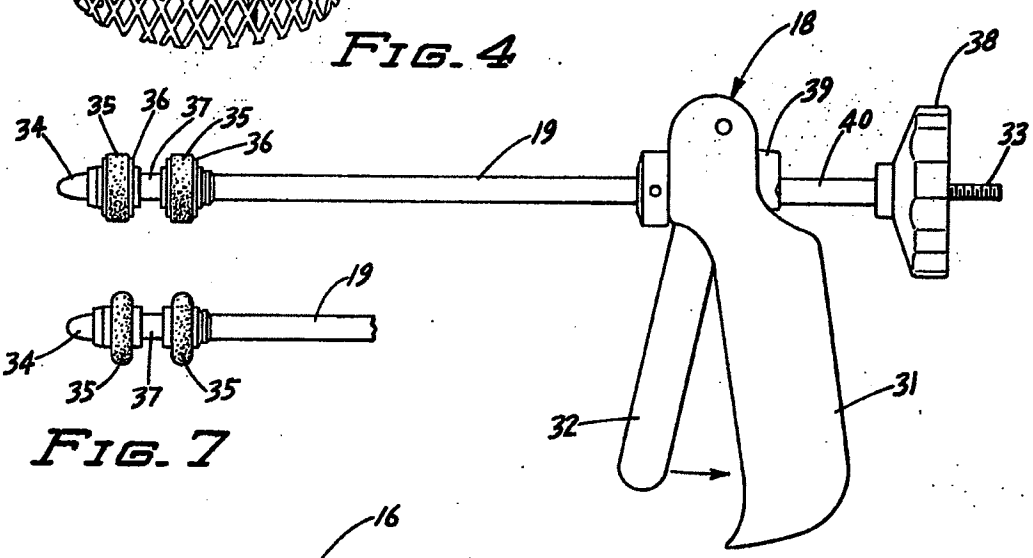

FIG. 6

FIG. 7

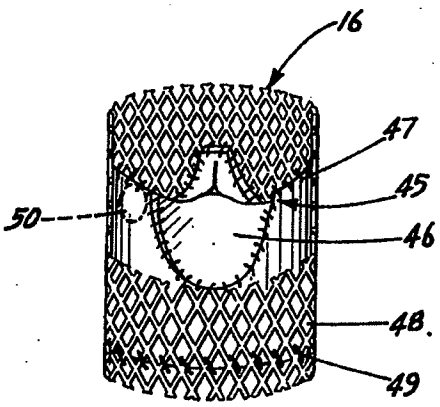

FIG. 8

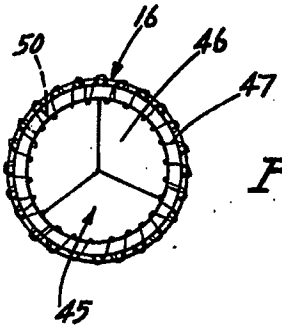

FIG. 9

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METHOD FOR FIXING PROSTHETIC IMPLANTS IN A LIVING BODY

This invention relates to a device and method for the rapid positive fixation of implanted prosthetic members in a living being. Many thousands of implants of prosthetic members, either artificial members or homografts or grafts from other animal species are made annually. Vessel grafts and heart valve implants are becoming commonplace. Transplantation of large organs such as the heart, lungs, liver, etc. is taking place in ever increasing numbers.

The fixation device according to the present invention comprises a tubular sleeve of deformable material to which the prosthetic member is secured and which is capable of being expanded radially into intimate engagement with the tissue surrounding the implant situs. It has been found through animal experimentation that the implant may be made rapidly and positively, without fear of dislodgment or leakage. When formed of a compatible material, the fixation device is well tolerated by the body and becomes completely covered by tissue leaving no exposed surface for the formation of clots and thrombi.

According to the prior art, artificial heart valves are installed by the careful placing of a plurality of stitches around the rim of tissue that will house the valve. These stitches are passed through a suture ring around the outside of the heart valve. The valve to be implanted is held outside of the heart 6 or 8 inches and each stitch is brought up through the suture ring while the valve is still so held. When the sewing is finished, the valve stands some distance above the heart and has 20 or 30 sutures going down to the tissue where it will finally rest. The sutures are held tight and the heart valve is slid down them into place and each suture is then individually tied. This process takes 30 to 45 minutes in the best hands and from an hour to an hour and one-half in the less then best.

In the case of the transplantation of a graft valve from another patient or from an animal, sewing takes more than an hour. Although excellent results have been reported with these transplanted valves, few surgeons are using them today because of the great time that must be taken to sew them in. Valve installation takes place while the patient is on an artificial heart-lung machine and every minute is very important.

One form of prior art heart valve is available wherein a caged ball valve is provided in its outer rim with a plurality of radially extending teeth which by screw means are caused to engage the aortic wall. Such valves, though expensive, are satisfactory where there is a very tight initial fit and where the aortic wall is of uniform consistency and size, conditions which cannot always be depended upon to exist. Accordingly, problems have arisen relating to aortic incompetence due to blood flow working its way between the prosthesis and the aortic wall in the many instances where no positive fixation is achieved by the tooth members.

The device of the present invention permits instant and positive fixation of heart valves, vessel grafts and other prosthetic members. The valve or other prosthetic member is prepared for implantation by attachment to the openwork sleeve. The valve and its skirt composed of the sleeve is assembled on an expanding tool device. This assembly can be quickly and easily forced into place and the tubular sleeve expanded to hold the valve or other member in place. This is done in a small fraction of the time required for other transplants so that in many instances use of the heart-lung machine is not required. The fixation sleeve expands so that a snug fit is assured regardless of the size, shape or consistency of the tissue wall at the implantation situs. Since the sleeve becomes incorporated into the tissue wall, no foreign material is left in contact with the blood, as opposed to prior art devices.

The invention is illustrated by the accompanying drawings in which:

FIG. 1 is a schematic view showing three stages of the grafting of an artificial bifurcation vessel graft utilizing the fixation device according to the present invention;

FIG. 2 is a perspective schematic view of one modified form of prosthetic fixation device;

FIG. 3 is a perspective view of another modification;

FIG. 4 is a perspective view of a further modification;

FIG. 5 is a schematic representation of a portion of the perimeter of any one of the devices of the preceding FIGS., as seen in transverse section;

FIG. 6 is an elevation of one form of expanding tool which may be utilized with the fixation device;

FIG. 7 is a fragmentary elevation of the operating end of the expanding tool showing the tool in expanded condition;

FIG. 8 is a perspective elevational view with the upper half of the fixation device in section, and showing the fixation device with a heart valve attached for implantation; and

FIG. 9 is a top plan view of the assembly of FIG. 8.

Referring to the drawings, and particularly to FIG. 1, there is shown schematically one manner in which the prosthesis fixation device according to the present invention is used. This use is illustrated with respect to the implantation of an artificial bifurcated aortic Dacron graft, indicated generally at 10, between the severed aorta 11, shown with a Satinsky clamp preventing flow, and the common iliac arteries 13 and 14. A completed joint is shown between the artery 13 and one branch 15 of the artificial vessel transplant. The ends of the artery and prosthesis are in butting relation held by an expanded fixation sleeve, indicated generally at 16, within the host-prosthesis junction. A similar sleeve 16 is shown partially within the branch 17 of the prosthesis 10 about to be connected to the artery 14.

The manner in which the junction is made is shown with respect to the severed end of the aorta 11. An expandable sleeve fixation device 16 is shown extending from the end of the artificial vessel graft 10 with about half of its length engaging the inside wall of the graft. The head of an expander tool, indicated generally at 18, whose tubular barrel 19 extends through a slit 20 in the graft, is positioned within the sleeve. A tapered tip 21 placed on the end of the expanding tool facilitates entry of the assembled graft, tool and fixation device 16 into the aorta. When in place, with the ends of aorta 11 and graft 10 butting, the sleeve is expanded by operation of the expanding tool to force the fenestrations of the sleeve into the wall of the aorta to achieve a leak-proof union and forcing the walls of the sleeve into tighter engagement with the inside wall of the graft 10.

After the sleeve is expanded, the tool is withdrawn. A smaller headed tool is inserted through slit 20 from the opposite direction to within the fixation device 16 of lesser diameter for connection with artery 14. The exposed end of sleeve 16 is inserted into the lumen of the artery 14 and the sleeve is expanded to make the joint. The tool is withdrawn, slit 20 is clamped shut and clamp 12 is removed to permit resumption of blood flow. The entire transplant can be made in a matter of a very few minutes to the point of restoration of the blood supply. The longitudinal slit in the graft may then be sewn closed at leisure in confidence that the blood is being supplied distal to the graft site.

The tubular sleeve 16 is made of deformable material such that it retains its expanded dimensions after expansion in place. It is formed from a non-toxic material compatible with blood and other body fluids, such as stainless steel. Its walls desirably have a large percentage of open area so as to permit proliferation of the intima of the vessels through the openings and over the intervening strand-like or ribbon-like members. Preferably the openwork sleeve is formed from so-called "expanded metal" sheeting which is produced by forming a series of staggered parallel slits in an impervious metal sheet and then stretching the sheet in a direction perpendicular to the slits to open the slits into apertures and expand the metal sheet in that direction while contracting it slightly in the opposite direction. The stretching operation by which the metal sheet is expanded imparts a twist or bend to the undulating flat ribbon-like portions 22 of the metal sheet separating the diamond-shaped apertures 23 which are generally uniformly sized and distributed. This twisting or bending of the metal members 22 between adjacent apertures imparts an angle or direction to the apertures themselves and to the ribbon-like members.

The expanded metal sheeting is desirably not flattened prior to forming into a sleeve. The result, as seen schematically in FIG. 5, is that the ribbon-like portions 22 of the sleeve extend angularly relative to the perimeter of the sleeve providing a multitude of narrow projecting edges which embed themselves into the tissue wall upon expansion of the sleeve. After being formed with the members 22 extending generally longitudinally, the sleeve is desirably spot welded to form a longitudinal seam. The tubular sleeve may be circular, oval, or polygonal (hexagonal, octagonal or the like) in cross-section. The cross-sectional area may be uniform along the length of the sleeve or it may vary, giving the sleeve generally a barrel shape or that of a truncated cone. The edges may be cuffed if desired or simply smoothed to facilitate entry. The sleeve may easily be expanded by about 50 percent beyond its original diameter. The sleeves are formed to be a size appropriate for the implant being made. The strands 22 and apertures 23 are sized proportionately.

Because of the twisted relation of the ribbon-like portions of the sleeve, protrusion of the vessel lining is facilitated with the result that very little metal is actually in contact with the blood stream. Experimentally it has been determined that within a few seconds a fine clot layer is laid down over the stainless steel struts forming a physiological bridge from the islands of intima where the vessel lining protrudes through the apertures in the sleeve.

Instead of metal, the tubular fixation sleeve may be formed from other natural or synthetic materials having the requisite properties and characteristics permitting the sleeve to be expanded into secure attachment with surrounding tissue. Desirably the material is one which is capable of being absorbed over an extended period of time by the tissue to which the sleeve is attached. A number of such absorbable materials are known.

In the form of fixation device shown in FIG. 2, sleeve 16A is provided with a plurality of circular holes 24 (which are of larger area than apertures 23) punched through the openwork wall around the sleeve adjacent one end to allow for the ostia of the coronary arteries.

In FIG. 3, a modified form of sleeve 16B is provided with a plurality of relatively large rectangular openings 25 extending longitudinally to permit exposure of wide areas around the coronary artery ostia. This form of fixation device is intended for the implantation of heart valves. The valve is hung with its commissures secured along the upper and lower ring portions 26 and 27, respectively, whose widths are about one-eighth to one-fourth the length of the sleeve.

In FIG. 4, the fixation device includes a plurality of longitudinal wire struts 28 separating two expandable and relatively narrow metal mesh ring sections 29 and 30. A three-pronged commissure valve is inserted in the upper expandable ring section 29 and secured to the bottom mesh ring 30 circumferentially.

A variety of expanding devices may be used to set the fixation devices in place. One form of such tool is shown in FIG. 6. The device includes a pistol-grip handle 31 and a trigger-like operating lever 32 pivoted therein. An elongated tubular barrel 19 extends out from the handle means. A concentric rod 33 extends through the handle 31 and barrel 19 terminating in a fitting 34 beyond the muzzle end of barrel 19 at its forward tip. Expansion means, comprised of a pair of resilient rings 35, each held between a pair of washers 36 and held spaced apart by a rigid spacer ring 37, are disposed between the muzzle end of barrel 19 and tip fitting 33. Operation of the lever 32 by gripping and squeezing to move it toward the handle causes rod 33 to shorten its exposed length in relation to barrel 19 such that squeezing force causes the resilient rings to decrease their longitudinal dimensions. Being non-compressible, they expand radially outwardly increasing their lateral dimensions, as shown in FIG. 7. In this way, a predictable dependable amount of expansion can be achieved. The breech end of rod 33 is threaded and fitted with a knurled knob 38. The heel 39 of operating lever 32 bearing against a spacer tube 40, which in turn bears against knob 38, causes the relative movement between barrel 19 and rod 33. Alternatively, force may be exerted simply by rotation of knob 38 and adjustment of the at-rest force exerted upon the expansion rings may be made. One, two or more expandable rings 35 may be used. The pattern of expansion can be predetermined as desired by selection of appropriate spacing between those rings.

When used for the installation of artificial vessel grafts made of Dacron, Teflon or similar artificial materials, the fixation sleeve is attached to the vessel graft some time prior to surgery and a longitudinal slit is made in the middle of the graft for the introduction of the expansion tool. At the time of surgery, the ends of the vessel to be grafted are secured through simple stay stitches or small clamps so that the fixation sleeve can be introduced thereto. The expander tool is in place in one of the sleeves at the time of introduction. This sleeve is then expanded in situ and the expander tool is removed through the longitudinal slit, turned around and used to expand the fixation sleeve at the other end and again removed. The longitudinal slit is clamped and the clamps or stitches securing the vessels to be grafted are removed to restore the blood flow. Very rapid fixation of vessel grafts is thus possible.

In FIG. 8 there is shown an aortic heart valve 45 in place in a fixation sleeve 16. The rim of valve 45 adjacent the cusps 46 is attached by sutures 47 to the sleeve near one end. A segment of the donor aorta 48 is attached by sutures 49 near the other end of sleeve 16. The opening 50 in the aorta wall for a coronary artery can be matched with the corresponding opening in the wall of the donee aorta.

When used for the fixation of heart valves, whether a transplant or artificial, the valve is secured within the fixation sleeve prior to surgery and the sleeve is assembled in the expansion tool. Then, at the time of surgery, the sleeve is rapidly expanded into place and the tool withdrawn. When used for implantation of heart valves in the aortic position, a total introduction time of only a few minutes is necessary. This means that an aortic valve may be placed without use of a heart-lung machine. Inflow of blood into the heart is occluded by placing clamps across the appropriate vessels. A longitudinal slit (aortotomy) is placed in the aorta just a few centimeters above where it begins. This slit is opened and the existing defective valve is removed. The new valve housed in the expandable sleeve is then placed in position and the sleeve is expanded in one stroke of the expanding tool. The expansion tool is then removed through the aortic slit and a clamp placed over it, thus allowing the restoration of blood flow so that only a few minutes total introduction time is required. The aortotomy can then be repaired at leisure after the heart has taken over its pumping function.

It is apparent that many modifications and variations of this invention as hereinbefore set forth may be made without departing from the spirit and scope thereof. The specific embodiments described are given by way of example only and the invention is limited only by the terms of the appended claims.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A method for rapidly and positively fixing an inplanted prosthetic device in a living body which comprises:

A. securing the prosthetic device to be implanted to at least one openwork tubular sleeve of non-toxic deformable material compatible with body fluids and capable of being expanded radially, said sleeve being of a diameter corresponding to the prosthetic member to be implanted and adapted for attachment to the prosthetic member, and including a plurality of longitudinally extending ribbon-like undulating portions disposed angularly with respect to the perimeter of said sleeve and interconnected to define a plurality of staggered closely spaced apertures,

B. introducing the sleeve and prosthetic device into a prepared transplant situs, and

C. expanding the sleeve radially outwardly against the tissue walls of said situs and forcing the undulating ribbon-like

portions of the sleeve into intimate engagement therewith, whereby the tissue may grow through and around the sleeve to cover the same.

2. A method according to claim 1 further characterized in that:

A. said prosthetic device to be implanted is a vessel graft,

B. said openwork sleeve is inserted partially and secured in each end of said vessel graft leaving an exposed portion of sleeve extending therefrom,

C. said graft is provided with a longitudinal opening to receive a sleeve expanding tool;

D. said prosthetic device and sleeves are joined to the host vessels to be grafted by introduction of the exposed portions of said sleeves into the severed host vessels, and

E. the sleeves are expanded radially outwardly into intimate engagement with the walls of said vessels and said graft.

3. A method according to claim 1 further characterized in that:

A. said prosthetic device to be implanted is a heart valve,

B. said valve is secured within one end of said sleeve,

C. said sleeve and valve are introduced into the situs of the defective valve to be replaced, and

D. said sleeve is expanded into engagement with the surrounding tissue.

* * * * *

EXHIBIT D

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

CORDIS CORPORATION,

Plaintiff-Cross Appellant,

—v.—

MEDTRONIC AVE, INC.,

Defendant-Appellant,

—and—

BOSTON SCIENTIFIC CORPORATION and BOSTON SCIENTIFIC SCIMED, INC.
(formerly known as Scimed Life Systems, Inc.),

Defendants-Appellants.

(*Caption continued on inside cover*)

APPEALS FROM THE UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF DELAWARE IN CONSOLIDATED CASES 97-CV-550, 97-CV-700 AND 98-CV-19,
JUDGE SUE L. ROBINSON.

BRIEF OF DEFENDANTS-APPELLANTS BOSTON SCIENTIFIC CORPORATION AND BOSTON SCIENTIFIC SCIMED, INC.

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September 11, 2006

POINT IV THE DISTRICT COURT ERRONEOUSLY AND PREJUDICIALLY PREVENTED BSC FROM RESPONDING TO CORDIS'S IRRELEVANT EVIDENCE ABOUT HOW USING A BALLOON TO DELIVER AND EXPAND A METAL TUBE WAS NOT OBVIOUS

A new obviousness trial for claim 23 is required because the district court committed prejudicial error by excluding relevant and admissible evidence that would have undercut the nexus between Cordis's nonobviousness evidence and the claim. Specifically, the court permitted Cordis to introduce irrelevant and confusing evidence that the general concept of using a balloon to deliver and expand a metal tube in an artery was not obvious, while preventing BSC from responding by pointing out that this method is claimed in other claims and patents, not device claim 23.

Claim 23 is an apparatus claim whose patentability depends on the claimed structure. *See Gardiner*, 171 F.2d at 315-16; *Stattmann*, 146 F.2d at 292. However, Cordis's presentation at trial did not address whether the structure of the claim 23 was obvious in view of the structure of the Ersek sleeve. Instead, Cordis presented evidence that the general concept of using a balloon to deliver and expand a metal tube in an artery was not obvious. In particular, Cordis devoted its presentation to asserting that this noninvasive method—which is claimed by other '762 claims and the '665 patent, but not by claim 23—was not obvious in view of the invasive surgical method described by Ersek. A5054-55/492:21-93:12;

A5056/500:5-9; A5048-49/468:20-69:10; A5054-56/492:21-500:12; A5262/1319:1-23; A5263/1321:1-10. Cordis also treated all the extensive praise and success of the balloon expandable coronary stent industry as though it derived solely from the rigid slotted-tube structure of claim 23, as opposed to the '665 patent and patents on flexible stents. A5108/704:17-24; A5109/706:7-07:17.

Cordis's evidence and arguments very likely confused the jury by distracting them from focusing on BSC's clear and convincing evidence that the structure of claim 23 is almost identical to the structure of the Ersek sleeve, that the minor differences are so trivial that the claimed structure would have been obvious, and that there was a motivation to modify the Ersek sleeve to arrive at the claimed structure. A5151/875:1-18; A5152-53/881:20-82:1; A5162/920:18-21:7; A5164-71/929:2-57:13; A27473-78; A27479-81.

Despite Cordis's confusing and misleading presentation, the district court—which believes that Ersek is different because of its different described use (Point II.A.2)—repeatedly ruled that BSC could not respond by explaining the differences between claim 23 and these other inventions in order to properly focus the jury on the obviousness of the claim and the irrelevance of Cordis' evidence. A5070-72/552:10-60:25; A5140-41/833:21-37:22; A5143/843:16-45:21. The court also prevented BSC from responding by telling the jury about Cordis's admission during "Project Olive"—Cordis's evaluation and proposed acquisition of the more

flexible NIR for $335 million to replace its less flexible Palmaz-Schatz stent—that Cordis considered the NIR's increased flexibility (as opposed to the slotted-tube structure) to be paramount to commercial success. A140; A5142/838:10-39:16; A22733-41; A27123-24.

This exclusion was prejudicial error because there was no basis for excluding this relevant and admissible evidence, which would have undercut the nexus between Cordis's evidence and the claim, apart from the court's unsupported concern about jury confusion (A124-126). In fact, BSC's evidence would have ameliorated, and its exclusion only exacerbated, the existing confusion caused by Cordis. The court abused its discretion by excluding this evidence, and a new trial is required because it is not "highly probable" that the error did not affect the verdict. *McQueeney*, 779 F.2d at 928.

EXHIBIT E

REDACTED